

DEC 16 2010

K102029

510(k) Summary:

PEAK Surgery System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

1. Submitter Name and Address:

PEAK Surgical, Inc.
2464 Embarcadero Way
Palo Alto, CA 94303
Phone: 650-331-3020
Fax: 650-331-3293

Contact: Lois Nakayama
Sr. Manager, Regulatory Affairs

Date prepared: July 15, 2010

2. Device Name:

Trade Name: PEAK Surgery System: PULSAR Generators and
PlasmaBlade Tissue Dissection Devices

Common Name: Electrosurgical Device and Accessories

Classification Name: Electrosurgical Cutting and Coagulation Device and
Accessories

Regulation Number: 21 CFR § 878.4400

Product Code: GEI

Regulatory Class: Class II

3. Predicate Devices:

PEAK Surgery System: PULSAR Generator and PlasmaBlade Tissue
Dissection Devices (K082786)

4. Device Description:

The PEAK Surgery System consists of the PULSAR II Generator, PEAK PlasmaBlade Tissue Dissection Devices and an optional wireless footswitch. The PULSAR II Generator is a microcontroller based, isolated output, electrosurgical unit that has been designed to produce monopolar RF energy for cutting and coagulation during surgery. The PULSAR II Generator is used with the PEAK PlasmaBlade Tissue Dissection Devices which are single use, sterile handpieces for monopolar energy delivery. The PlasmaBlade Tissue Dissection Devices consist of an insulated blade electrode, rotating shaft, handle with integrated controls and a cable. An optional footswitch may be used to operate the system in lieu of the controls on the PlasmaBlade handpieces.

The PULSAR II Generator is a modification of the PULSAR Generator

5. Intended Use:

The PEAK Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.

6. Technological Characteristics

The PEAK PULSAR II Generator is similar to the predicate device in design specifications, output energy, and delivery system. They are both electrosurgical instruments designed to produce monopolar RF energy for cutting and coagulation during surgery. The modifications to the hardware, circuitry and operating frequency do not significantly affect the safety or effectiveness of the device.

7. Performance Data:

Laboratory and performance tests were executed to ensure that the device functioned as intended and met design specifications. Sufficient data were obtained to show that the device is substantially equivalent to the predicate device and meets safety and effectiveness criteria.

8. Sterilization

The PULSAR II Generator is not supplied sterile and is not intended to be sterilized.

9. Conclusion:

By virtue of design, materials function and intended use, the PEAK PULSAR II is as safe, as effective and performs as well as or better than the predicate device. In establishing substantial equivalence to the predicate device, PEAK Surgical evaluated the indications for use, product specifications and energy requirements of the device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 16 2010

PEAK Surgical, Inc.
% Ms. Lois Nakayama
2464 Embarcadero Way
Palo Alto, California 94303

Re: K102029

Trade/Device Name: PEAK Surgery System (PULSAR® Generators and PEAK
PlasmaBlade® Tissue Dissection Devices)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical cutting and coagulation device and accessories

Regulatory Class: Class II

Product Code: GEI

Dated: November 12, 2010

Received: November 15, 2010

Dear Ms. Nakayama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

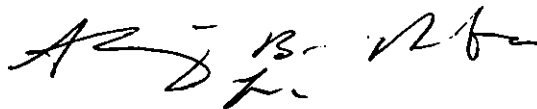
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

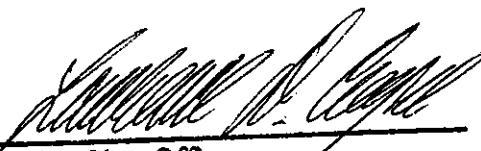
Indications for Use

510(k) Number (if known): _____

Device Name: PEAK Surgery System (PULSAR® Generators and PEAK PlasmaBlade®
Tissue Dissection Devices)

Indications for Use:

The PEAK Surgery System is indicated for cutting and coagulation of soft tissue during General, Plastic and Reconstructive (including but not limited to skin incisions and development of skin flaps), ENT, Gynecologic, Orthopaedic, Arthroscopic, Spinal and Neurological surgical procedures.


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102029

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)